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United States Senate

COMMITTEE ON
HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS
WASHINGTON, DC 20510-6250

KEITH B. ASHDOWN, STAFF DIRECTOR
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March 25, 2015

The Honorable Gina McCarthy
Administrator
Environmental Protection Agency
U.S. EPA Headquarters – William J. Clinton Building
1200 Pennsylvania Avenue, Northwest
Washington, DC 20460

Dear Administrator McCarthy:

Our nation has faced serious threats from several infectious disease outbreaks—including those occurring due to Ebola, Measles, and novel strains of avian influenza—in the last year. As you know, there have also been concerning reports of misplaced vials of smallpox and other high-risk pathogens at government research facilities throughout the country.¹ These events are reminders as to how vulnerable our nation may be to a serious biological incident. Our committee takes seriously our oversight responsibilities in how federal agencies are working to prepare for and respond to these potential threats to our national security.

We are concerned about reports of what appears to be an accidental infection of several rhesus macaques with *Burkholderia pseudomallei*, or *B. pseudomallei*, at the Tulane National Primate Research Center.² Our understanding is that the first macaque infections were identified in November, with several more cases discovered over the last few months. These macaques were housed in outdoor cages while they were symptomatic and before their infections were identified as resulting from *B. pseudomallei*. News accounts suggest that hundreds of macaques may have been exposed to the bacteria, and that the soil and water in and around the facility have been tested for contamination. Although it is unclear how and when the transmission occurred, an investigation by the Centers for Disease Control and Prevention (CDC), the U.S. Environmental Protection Agency (EPA) and the U.S. Department of Agriculture (USDA) into how the exposure to the bacteria occurred has revealed that lapses in the use of personal protective equipment may have been at fault.³

¹ For example, see Alison Young, "Reports reveal safety violations at many bioterror labs," *USA Today*, July 16, 2014.

² Alison Young, "Deadly bacteria release sparks concern at Louisiana lab," *USA Today*, March 5, 2015.

³ Alison Young, "Sloppy lab practice cited in bioterror bacteria release," *USA Today*, March 13, 2015.

As you know, *B. pseudomallei* has been identified as a “material threat” by the Department of Homeland Security and a potential bioterrorism agent by the CDC.⁴ Summarizing the threat posed by *B. pseudomallei*, a Department of Defense-funded review of the bacteria states, “Detection is difficult, treatment of [the resulting] melioidosis is long, relapse is frequent, and a vaccine is lacking.”⁵ Identifying and learning more about how the transmission of these bacteria occurred from a biosafety level 3 facility to one not prepared to handle such an agent in any way is imperative.

A recent *USA Today* review of the federal investigation into the cause of the incident has also raised several other potential concerns about the scope of that investigation.⁶ First, according to the *USA Today* story, the soil sampling plan implemented by the EPA to study contamination in the primate facility might have been inadequate.⁷ By looking at peer-review research conducted on the subject, the newspaper concluded that a proper soil sampling for *B. pseudomallei* could require a much higher number of samples collected compared to what the EPA and the state implemented. Second, the article raised suggestions that soil scientists at the USDA may have a limited understanding of whether *B. pseudomallei* can survive in U.S. soil.⁸

As we seek to understand the implementation and progress of the federal review of this incident, we respectfully request that you assist the Committee’s oversight by providing the following information no later than April 8, 2015:

1. An explanation of the EPA’s scientific justification for the soil sampling plan used in the federal investigation at the Tulane National Primate Research Center, particularly as it pertains to the number of soil samples taken at the site, and whether the agency has sought outside input or consultation about that plan (if so, please provide us with a list of those partners).
2. A description of the procedure and specific equipment used by the EPA for air sampling pursuant to this investigation.
3. A copy of the State of Louisiana’s letter to the EPA requesting assistance in testing soil for *B. pseudomallei*.
4. A delineation of responsibilities among federal agencies for soil and air sampling in the wake of this and other events involving potential bioterrorism agents or infectious diseases.

The Committee on Homeland Security and Governmental Affairs is the chief investigative committee of the United States Senate. Rule XXV of the Standing Rules of the Senate authorizes the Committee to investigate “the efficiency, economy, and effectiveness of all

⁴ U.S. Department of Health and Human Services, “2012 Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Strategy.”
Centers for Disease Control and Prevention, “Bioterrorism Agents/Diseases,”
<http://www.bt.cdc.gov/agent/agentlist.asp>.

⁵ Timothy J. J. Inglis and Jose-Luis Sagripanti. (2006) “Minireview: Environmental Factors That Affect the Survival and Persistence of *Burkholderia pseudomallei*,” *Applied and Environmental Microbiology*, vol. 72 (11): 6865-75.

⁶ Alison Young, “Deadly bacteria release sparks concern at Louisiana lab,” *USA Today*, March 5, 2015.

⁷ Alison Young, “Deadly bacteria release sparks concern at Louisiana lab,” *USA Today*, March 5, 2015.

⁸ Alison Young, “Deadly bacteria release sparks concern at Louisiana lab,” *USA Today*, March 5, 2015.

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March 25, 2015
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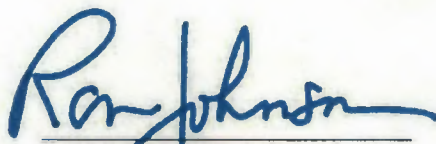
agencies and departments of the Government.”⁹ Additionally, S. Res. 73 (114th Congress) authorizes the Committee to examine “the efficiency and economy of operations of all branches and functions of Government with particular references to (i) the effectiveness of present national security methods, staffing, and processes”

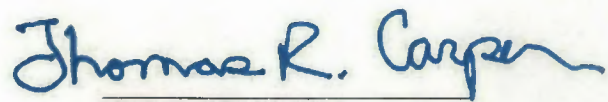
Thank you for your attention to this issue. As your investigation continues, we ask that you keep us apprised of any progress or issues that may not be addressed in this letter. We know you share our goal of ensuring the safety and efficiency of our nation’s biosafety research enterprise.

If your staff has any questions, they may contact Gabe Sudduth, of the Majority Committee staff, at (202) 224-4751, and Robert Bradley of the Minority Committee staff, at (202) 224-2627.

With best personal regards, we are

Sincerely yours,



Ron Johnson
Chairman

Thomas R. Carper
Ranking Member

Enclosure

⁹ S. Rule XXV(k); *see also* S. Res. 445, 108th Cong. (2004).

Instructions for Responding to a Committee Request
Committee on Homeland Security and Governmental Affairs
United States Senate
114th Congress

A. Responding to a Request for Documents

1. In complying with the Committee's request, produce all responsive documents that are in your possession, custody, or control, whether held by you or your past or present agents, employees, and representatives acting on your behalf. You should also produce documents that you have a legal right to obtain, that you have a right to copy or to which you have access, as well as documents that you have placed in the temporary possession, custody, or control of any third party. Requested records, documents, data, or information should not be destroyed, modified, removed, transferred, or otherwise made inaccessible to the Committee.
2. In the event that any entity, organization, or person denoted in the request has been or is also known by any other name or alias than herein denoted, the request should be read also to include the alternative identification.
3. The Committee's preference is to receive documents in electronic form (i.e. CD, memory stick, or thumb drive) in lieu of paper productions.
4. Documents produced in electronic form should also be organized, identified, and indexed electronically.
5. Electronic document productions should be prepared according to the following standards:
 - a. The production should consist of single page Tagged Image Files (".tif"), files accompanied by a Concordance-format load file, an Opticon reference file, and a file defining the fields and character lengths of the load file.
 - b. Document numbers in the load file should match document Bates numbers and .tif file names.
 - c. If the production is completed through a series of multiple partial productions, field names and file order in all load files should match.
 - d. All electronic documents produced should include the following fields of metadata specific to each document:

BEGDOC, ENDDOC, TEXT, BEGATTACH, ENDATTACH, PAGECOUNT, CUSTODIAN, RECORDTYPE, DATE, TIME, SENTDATE, SENTTIME, BEGINDATE, BEGINTIME, ENDDATE, ENDTIME, AUTHOR, FROM, CC, TO, BCC, SUBJECT, TITLE, FILENAME, FILEEXT, FILESIZE, DATECREATED, TIMECREATED, DATELASTMOD, TIMELASTMOD, INTMSGID, INTMSGHEADER, NATIVELINK, INTFILPATH, EXCEPTION, BEGATTACH.

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- e. Alternatively, if the production cannot be made in .tif format, all documents derived from word processing programs, email applications, instant message logs, spreadsheets, and wherever else practicable should be produced in text searchable Portable Document Format (".pdf") format. Spreadsheets should also be provided in their native form. Audio and video files should be produced in their native format, although picture files associated with email or word processing programs should be produced in .pdf format along with the document it is contained in or to which it is attached.
 - f. If any of the requested information is only reasonably available in machine-readable form (such as on a computer server, hard drive, or computer backup tape), consult with the Committee staff to determine the appropriate format in which to produce the information.
- 6. Documents produced to the Committee should include an index describing the contents of the production. To the extent more than one CD, hard drive, memory stick, thumb drive, box or folder is produced, each CD, hard drive, memory stick, thumb drive, box or folder should contain an index describing its contents.
 - 7. Documents produced in response to the request should be produced together with copies of file labels, dividers or identifying markers with which they were associated when the request was served.
 - 8. When producing documents, identify the paragraph in the Committee's schedule to which the documents respond.
 - 9. Do not refuse to produce documents that any other person or entity also possesses non-identical or identical copies of the same documents.
 - 10. This request is continuing in nature and applies to any newly discovered information. Any record, document, compilation of data or information not produced because it has not been located or discovered by the return date, should be produced immediately upon subsequent location or discovery.
 - 11. All documents should be Bates-stamped sequentially and produced sequentially. Each page should bear a unique Bates number.
 - 12. Two sets of documents should be delivered, one set to the Majority Staff and one set to the Minority Staff. When documents are produced to the Committee, production sets should be delivered to the Majority Staff in Room 340 of the Dirksen Senate Office Building and the Minority Staff in Room 344 of the Dirksen Senate Office Building.
 - 13. If compliance with the request cannot be made in full by the date specified in the request, compliance should be made to the extent possible by that date. Notify Committee staff as soon as possible if full compliance cannot be made by the date specified in the request, and provide an explanation for why full compliance is not possible by that date.

Instructions for Responding to a Committee Request

14. In the event that a document is withheld on the basis of privilege, provide a privilege log containing the following information concerning any such document: (a) the privilege asserted; (b) the type of document; (c) the general subject matter; (d) the date, author and addressee; and (e) the relationship of the author and addressee to each other.
15. If any document responsive to this request was, but no longer is, in your possession, custody, or control, identify the document (stating its date, author, subject and recipients) and explain the circumstances under which the document ceased to be in your possession, custody, or control.
16. If a date or other descriptive detail set forth in this request referring to a document is inaccurate, but the actual date or other descriptive detail is known to you or is otherwise apparent from the context of the request, produce all documents which would be responsive as if the date or other descriptive detail were correct.
17. In the event a complete response requires the production of classified information, provide as much information in unclassified form as possible in your response and send all classified information under separate cover via the Office of Senate Security.
18. Unless otherwise specified, the period covered by this request is from January 1, 2009 to the present.
19. Upon completion of the document production, you should submit a written certification, signed by you or your counsel, stating that: (1) a diligent search has been completed of all documents in your possession, custody, or control which reasonably could contain responsive documents; and (2) all documents located during the search that are responsive have been produced to the Committee.

B. Responding to Interrogatories or a Request for Information

1. In complying with the Committee's request, answer truthfully and completely. Persons that knowingly provide false testimony could be subject to criminal prosecution for perjury or for making false statements. Persons that knowingly withhold requested information could be subject to proceedings for contempt of Congress. If you are unable to answer an interrogatory or information request fully, provide as much information as possible and explain why your answer is incomplete.
2. In the event that any entity, organization, or person denoted in the request has been or is also known by any other name or alias than herein denoted, the request should be read also to include the alternative identification.
3. Your response to the Committee's interrogatories or information requests should be made in writing and should be signed by you, your counsel, or a duly authorized designee.

Instructions for Responding to a Committee Request

4. When responding to interrogatories or information requests, respond to each paragraph in the Committee's schedule separately. Clearly identify the paragraph in the Committee's schedule to which the information responds.
5. Where knowledge, information, or facts are requested, the request encompasses knowledge, information or facts in your possession, custody, or control, or in the possession, custody, or control of your staff, agents, employees, representatives, and any other person who has possession, custody, or control of your proprietary knowledge, information, or facts.
6. Do not refuse to provide knowledge, information, or facts that any other person or entity also possesses the same knowledge, information, or facts.
7. The request is continuing in nature and applies to any newly discovered knowledge, information, or facts. Any knowledge, information, or facts not provided because it was not known by the return date, should be provided immediately upon subsequent discovery.
8. Two sets of responses should be delivered, one set to the Majority Staff and one set to the Minority Staff. When responses are provided to the Committee, copies should be delivered to the Majority Staff in Room 340 of the Dirksen Senate Office Building and the Minority Staff in Room 344 of the Dirksen Senate Office Building.
9. If compliance with the request cannot be made in full by the date specified in the request, compliance should be made to the extent possible by that date. Notify Committee staff as soon as possible if full compliance cannot be made by the date specified in the request, and provide an explanation for why full compliance is not possible by that date.
10. In the event that knowledge, information, or facts are withheld on the basis of privilege, provide a privilege log containing the following information: (a) the privilege asserted; (b) the general subject matter of the knowledge, information, or facts withheld; (c) the source of the knowledge, information, or facts withheld; (d) the paragraph in the Committee's request to which the knowledge, information, or facts are responsive; and (e) each individual to whom the knowledge, information, or facts have been disclosed.
11. If a date or other descriptive detail set forth in this request is inaccurate, but the actual date or other descriptive detail is known to you or is otherwise apparent from the context of the request, provide the information that would be responsive as if the date or other descriptive detail was correct.
12. In the event a complete response requires the transmission of classified information, provide as much information in unclassified form as possible in your response and send all classified information under separate cover via the Office of Senate Security.
13. Unless otherwise specified, the period covered by this request is from January 1, 2009 to the present.

Instructions for Responding to a Committee Request

C. Definitions

1. The term “document” in the request or the instructions means any written, recorded, or graphic matter of any nature whatsoever, regardless of how recorded, and whether original or copy, including, but not limited to, the following: memoranda, reports, expense reports, books, manuals, instructions, financial reports, working papers, records, notes, letters, notices, confirmations, telegrams, receipts, appraisals, pamphlets, magazines, newspapers, prospectuses, inter-office and intra-office communications, electronic mail (e-mail), contracts, cables, notations of any type of conversation, telephone call, meeting or other communication, bulletins, printed matter, computer printouts, teletypes, invoices, transcripts, diaries, analyses, returns, summaries, minutes, bills, accounts, estimates, projections, comparisons, messages, correspondence, press releases, circulars, financial statements, reviews, opinions, offers, studies and investigations, questionnaires and surveys, and work sheets (and all drafts, preliminary versions, alterations, modifications, revisions, changes, and amendments of any of the foregoing, as well as any attachments or appendices thereto), and graphic or oral records or representations of any kind (including without limitation, photographs, charts, graphs, microfiche, microfilm, videotape, recordings and motion pictures), and electronic, mechanical, and electric records or representations of any kind (including, without limitation, tapes, cassettes, disks, and recordings) and other written, printed, typed, or other graphic or recorded matter of any kind or nature, however produced or reproduced, and whether preserved in writing, film, tape, disk, videotape or otherwise. A document bearing any notation not a part of the original text is to be considered a separate document. A draft or non-identical copy is a separate document within the meaning of this term.
2. The term “communication” in the request or the instructions means each manner or means of disclosure or exchange of information, regardless of means utilized, whether oral, electronic, by document or otherwise, and whether face to face, in meetings, by telephone, mail, telex, facsimile, email (desktop or mobile device), computer, text message, instant message, MMS or SMS message, regular mail, telexes, discussions, releases, delivery, or otherwise.
3. The terms “and” and “or” in the request or the instructions should be construed broadly and either conjunctively or disjunctively to bring within the scope of this subpoena any information which might otherwise be construed to be outside its scope. The singular includes plural number, and vice versa. The masculine includes the feminine and neuter genders.
4. The terms “person” or “persons” in the request or the instructions mean natural persons, firms, partnerships, associations, corporations, subsidiaries, divisions, departments, joint ventures, proprietorships, syndicates, or other legal, businesses or government entities, and all subsidiaries, affiliates, divisions, departments, branches, or other units thereof.
5. The term “identify” in the request or the instructions, when used in a question about individuals, means to provide the following information: (a) the individual’s complete name and title; and (b) the individual’s business address and phone number.

Instructions for Responding to a Committee Request

6. The terms “referring” or “relating” in the request or the instructions, when used separately or collectively, with respect to any given subject, mean anything that constitutes, contains, embodies, reflects, identifies, states, refers to, deals with or is pertinent to that subject in any manner whatsoever.
7. The term “employee” in the request or the instructions means agent, borrowed employee, casual employee, consultant, contractor, de fact employee, independent contractor, joint adventurer, loaned employee, part-time employee, permanent employee, provisional employee or subcontractor.
8. The terms “you” and “your” in the request or the instructions refer to yourself; your firm, corporation, partnership, association, department, or other legal or government entity, including all subsidiaries, divisions, branches, or other units thereof; and all members, officers, employees, agents, contractors, and all other individuals acting or purporting to act on your behalf, including all present and former members, officers, employers, agents, contractors, and all other individuals exercising or purporting to exercise discretion, make policy, and/or decisions.

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